NCT: 01333046

January 25, 2023

Administration of TAA-Specific CTLs; Hodgkin or Non-Hodgkin Lymphoma; TACTAL

H-27471- ADMINISTRATION OF TUMOR-ASSOCIATED ANTIGEN (TAA)-SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH ACTIVE OR RELAPSED HODGKIN OR NON-HODGKIN LYMPHOMA (TACTAL)

Background

This is a clinical trial, a type of research study. Your doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You have a type of lymph gland disease called Hodgkin or non-Hodgkin lymphoma which has come back, or may come back, or has not gone away after treatment, including the standard treatment we know for these diseases. We are asking you to volunteer to be in a research study using special immune system cells called tumor-associated antigen (TAA)-specific cytotoxic T lymphocytes, a new experimental therapy.

We have previously used this sort of therapy to treat Hodgkin or non-Hodgkin lymphoma that shows proof of infection with the virus that causes infectious mononucleosis ("mono" or the "kissing disease"), Epstein-Barr virus (EBV). EBV is found in cancer cells of up to half of all patients with Hodgkin's and non-Hodgkin lymphoma. This suggests that it may play a role in causing lymphoma. The cancer cells infected by EBV are able to hide from the body's immune system and escape being killed. We previously tested whether special white blood cells, called T cells, that were trained to kill EBV-infected cells could affect these tumors, and in many patients we found that giving these trained T cells caused a complete or partial response.

However, many patients do not have EBV in their lymphoma cells. Therefore, we now want to test whether we can direct these special T lymphocytes against other types of proteins that show on the tumor cell surface. We want to test whether this will result in similar promising results. The proteins that we will target in this study are called tumor-associated antigens (TAAs) - (these are cell proteins that are specific to the cancer cell, so they either do not show or show up in low quantities on normal human cells).

In this stage of the study, we will target from one to five TAAs which commonly show on lymphoma cells. These TAAs are called PRAME, SSX, MAGE, NY-ESO and Survivin. We will do this by using special types of T cells called cytotoxic T lymphocytes (CTLs) generated in the lab. These TAA-specific T cells are an investigational product not yet approved by the U.S. Food and Drug Administration.

This research study is sponsored by a NCI Lymphoma Specialized Program in Research Excellence (SPORE) grant.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of this study is to find out how many TAAs we can safely target with cytotoxic T cells, to learn what the side-effects are when targeting increasing numbers of TAAs, and to see whether this

therapy might help patients with Hodgkin disease or non-Hodgkin lymphoma.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

At most, 16 people may be treated on this stage of the study.

Earlier, you gave blood for us to make TAA-specific cytotoxic T cells in the lab. These cells were grown and frozen for you.

If the TAA-specific cytotoxic T cells can be made, the time from collection of the blood to manufacture of T cells for administration to the patient is about 1 to 2 months.

The cells will be injected by IV into you over 10 minutes. You may be pre-treated with acetaminophen (Tylenol) and diphenhydramine (Benadryl). Acetaminophen (Tylenol) and diphenhydramine (Benadryl) are given to prevent a possible allergic reaction to the T cell administration. Initially, two doses of T cells will be given four weeks apart. Your lymphoma will be assessed pre-infusion and then 4 weeks after the second infusion. If after your second infusion there is a reduction in the size of your lymphoma on CT or MRI scan as assessed by a radiologist, you can receive up to six (6) additional doses of the T cells at 6-8 week intervals if you wish. All of the treatments will be given by the Center for Cell and Gene Therapy at Houston Methodist Hospital or Texas Childrens Hospital.

In between the first and second T cell infusions and for 6 weeks after the last infusion, we ask that you not receive any other anti-cancer treatments such as radiation or chemotherapy. If you do receive any other therapies in-between the first and second infusion of T cells, you will be taken off treatment and will not be able to receive the second infusion of T cells.

This is a treatment escalation study. This means that at the beginning, patients will receive TAA-specific T cells targeting first 1 and then 2 TAAs. Once this schedule proves safe, the next group of patients will receive TAA-specific T cells targeting first 2 and then 3 TAAs. This process will continue until all 4 levels are studied. This means that the final cohort of patients will receive TAA-specific T cells targeting first 4 and then 5 TAAs. If the side-effects are too severe, the number of TAAs being targeted will be lowered or the T cell injections will be stopped.

To learn more about the way the T cells are working in your body, an extra 20-40 mL (4-8 teaspoons) of blood will be taken before each infusion, and at Weeks 1, 2, 4 and 6. One additional blood sample might be drawn 3 to 4 days post the T-cell infusion; this is optional. Please let your doctor know if it will be difficult for you to come in for this optional blood draw on Day 3 to 4. Afterwards, blood will be collected at 3, 6, 9 and 12 months after the last infusion. The blood may be drawn from your central line at the time of your regular blood tests. We will use this blood to see how long the T cells last, and to look at the immune response to your cancer.

These specimens and information about your circumstances may be used in other research being conducted in immune therapy. Although there will be a record identifying under what circumstances these specimens were obtained, under all circumstances your identity will be kept confidential.

There is a small risk for the loss of confidentiality. However, study personnel will make every effort to minimize this risk.

This study will continue until it has completed enrolling subjects.

We may request a sample of a previous tumor biopsy you have had or from a tumor biopsy performed at any time while you are on this study. The sample will be used for research purposes related to this study.

In the event of death, we will request permission to perform an autopsy to learn more about the effects of the treatment on your disease.

Study Duration: Your active participation in this study will last for approximately one (1) year. If you receive additional doses of the T cells as described above, your active participation will last until one (1) year after your last dose of T cells. We will then contact you once a year for up to 4 additional years (total of 5 years follow-up) in order to evaluate your disease response long-term.

If you decide to withdraw at any time during the study, both samples and data collected during your participation will be maintained.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning HIV
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, TCH: Texas Children's Hospital, TMH: The Methodist Hospital, and NATIONAL CANCER

INSTITUTE (NCI) and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL CANCER INSTITUTE (NCI) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College

of Medicine, Data and Safety Monitoring Board, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. George Carrum, MD
Houston Methodist Hospital,
Suite M964 6565 Fannin Street
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

Risks of Blood Draws are possible bleeding and infection at the puncture site. Also, it is possible that a person may faint when blood is drawn.

Risks of T Cell Administration: Similar types of T cells have been given to over 50 patients with lymphoma. Most patients had no side-effects. In some patients with large tumors and/or widespread disease, the cells have caused inflammation leading to fever and flu-like symptoms, as well as swelling at the tumor site. This swelling could be potentially dangerous and even life-threatening depending on the site. One area of the body where this inflammation could happen is in the lungs. Swelling in the lungs could be severe and possibly life-threatening. If you have such swelling, you may be given steroids which can help to treat this side-effect.

There is also a risk that the cells could cross-react with normal proteins in your body, rather than the tumor-associated antigens, and cause damage to normal organs. We try to reduce this risk by checking the cross-reactivity of the cells before we give them back to you.

A small percentage of patients that receive this type of therapy develop a life-threatening complication known as a cytokine release syndrome. This complication causes high body temperature, increased heart rate, and low blood pressure. This complication can be life threatening. There are treatments for this complication.

Risks of Acetaminophen (Tylenol): Rarely, large doses or long-term usage can cause liver damage, rash, itching, fever, and/or lowered blood sugar. These side-effects are unlikely at the doses being used for this study.

Risks of Diphenhydramine (Benadryl) include drowsiness, dizziness, headache, irritability, stomach

upset, vision changes (e.g. blurred vision), decreased coordination, and/or dry mouth/nose/throat.

General: Because of potential or unknown effects of the study on a fetus, if you are a woman of child-bearing potential, you must have a negative pregnancy test prior to the first and second infusions.

We will watch you very carefully for any side-effects. If there are bad side-effects, we will stop the treatment.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: that it is possible your immune system may begin to kill the cancer cells, making the lymphoma go into remission or go away. Additionally, your participation may help the investigators better understand how the immune system can fight Hodgkin and non-Hodgkin lymphoma. This could benefit other patients with lymphoma. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: No further treatment, or other treatment with chemotherapy and radiation. Your doctor will discuss these other options with you. Additionally, the same alternatives are available if after participation in this research project you are not responding to the therapy.

Subject Costs and Payments

You will not be charged for the manufacture or preparation of the T cell product, or for any evaluations that are being done solely as part of your participation in this research project. You may be charged for some research-related costs, including the infusion of the product. You will be charged for any tests or treatments that are being done as standard treatment for Hodgkin disease or non-Hodgkin lymphoma.

You will not be paid for taking part in this study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Research Related Injury

If you are injured as part of your participation in this study, there are no plans to pay you.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Women of Childbearing Potential

It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. Because of the potential risks involved, you or your partner should not become pregnant while you are participating in this study.

If you are sexually active or become sexually active and can get pregnant or can get your partner pregnant, you must agree to use one of the following forms of birth control every time you have sex and for (6) months afterwards:

* oral contraceptives ("the pill"),
* intrauterine devices (IUDs),
* contraceptive implants under the skin, or contraceptive injections,
* condoms with foam.

Should you become pregnant while on this study, you must immediately notify the study personnel.

The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can choose not to provide this information.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, GEORGE CARRUM, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: GEORGE CARRUM at 713-441-1450 during the day and after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

The National Institutes of Health (NIH) and the National Cancer Institute (NCI) may have access to your records for research purposes. Coded information may be provided to the NIH/NCI such as Patient ID, Patient zip code, Patient country code, and Patient birth date (month/year). However, in the event of an audit NIH/NCI might have access to more information that is part of your research record.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date

H-27471- ADMINISTRATION OF TUMOR-ASSOCIATED ANTIGEN (TAA)-SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH ACTIVE OR RELAPSED HODGKIN OR NON-HODGKIN LYMPHOMA (TACTAL)

Background

This is a clinical trial, a type of research study. Your doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You have a type of lymph gland disease called Hodgkin or non-Hodgkin lymphoma which has come back, or may come back, or has not gone away after treatment, including the standard treatment we know for these diseases. We are asking you to volunteer to be in a research study using special immune system cells called tumor-associated antigen (TAA)-specific cytotoxic T lymphocytes, a new experimental therapy.

We have previously used this sort of therapy to treat Hodgkin or non-Hodgkin lymphoma that shows proof of infection with the virus that causes infectious mononucleosis ("mono" or the "kissing disease"), Epstein-Barr virus (EBV). EBV is found in cancer cells of up to half of all patients with Hodgkin's and non-Hodgkin lymphoma. This suggests that it may play a role in causing lymphoma. The cancer cells infected by EBV are able to hide from the body's immune system and escape being killed. We previously tested whether special white blood cells, called T cells, that were trained to kill EBV-infected cells could affect these tumors, and in many patients we found that giving these trained T cells caused a complete or partial response.

However, many patients do not have EBV in their lymphoma cells; therefore we now want to test whether special T lymphocytes directed against other types of proteins that show on the tumor cell surface can result in similar promising results. The proteins that we will target in this study are called tumor-associated antigens (TAAs) - these are cell proteins that are specific to the cancer cell, so they either do not show or show up in low quantities on normal human cells.

In this stage of the study we will target five TAAs which commonly show on lymphoma cells, called NY-ESO-1, MAGEA4, PRAME, Survivin and SSX. We will do this by using special types of T cells called cytotoxic T lymphocytes (CTLs) generated in the lab. These TAA-specific T cells are an investigational product not yet approved by the U.S. Food and Drug Administration.

In addition, we will give you a drug called azacytidine before giving you the T cells. We hope that the combination helps the T cells work better.

Baylor College of Medicine has a financial interest with Marker Therapeutics, LLC, a licensee of Baylor College Medicine patented technologies. The study staff (Dr. Heslop, Dr. Leen and Dr. Rooney) also have a financial interest in the development of the study drug. They may benefit financially if this research leads to future treatment options. Please feel free to ask the study team if you have any questions about this relationship.

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This research study is sponsored by a NCI Lymphoma Specialized Program in Research Excellence (SPORE) grant.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of this stage of the study is to find out if it is safe to give TAA-specific cytotoxic T cells to patients in combination with azacytidine. We want to learn what the side-effects are, and to see whether this therapy might help patients with Hodgkin disease or non-Hodgkin lymphoma.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

At most, 15 people may be treated on this stage of the study.

Earlier, you gave blood for us to make TAA-specific cytotoxic T cells in the lab. These cells were grown and frozen for you.

If the TAA-specific cytotoxic T cells can be made, the time from collection of the blood to manufacture of T cells for administration to the patient is about 1 to 2 months.

You will be given 3 cycles of aza (administered daily through a vein for 5 days, every 28 days) followed by 2 doses of multiTAA-specific T cells administered 14 days apart. Before you are given the aza you will be given a drug to help prevent nausea and vomiting.

The cells will then be injected by IV into you over 10 minutes. You may be pre-treated with acetaminophen (Tylenol) and diphenhydramine (Benadryl). Acetaminophen (Tylenol) and diphenhydramine (Benadryl) are given to prevent a possible allergic reaction to the T cell administration. Initially, two doses of T cells will be given two weeks apart. Your lymphoma will be assessed before aza treatment, before T cell infusion and then 6 weeks after the second infusion. If after your second infusion there is a reduction in the size of your lymphoma on CT or MRI scan as assessed by a radiologist, you can receive up to six (6) additional doses of the T cells at 6-8 week intervals if you wish. All of the treatments will be given by the Center for Cell and Gene Therapy at Houston Methodist Hospital or Texas Children's Hospital.

In between the first and second T cell infusions and for 6 weeks after the last infusion, we ask that you not receive any other anti-cancer treatments such as radiation therapy or chemotherapy. If you do receive any other therapies in-between the first and second infusion of T cells, you will be taken off treatment and will not be able to receive the second infusion of T cells.

MEDICAL TESTS BEFORE TREATMENT

Before being treated, you will receive a series of standard medical tests:

- Physical exam.
- Blood tests to measure blood cells, kidney and liver function.
- Measurements of your tumor by routine imaging studies. We will use the imaging study that was used before to follow your tumor: CT, MRI, or PET.
- Pregnancy test if you are a female who can have children.

MEDICAL TESTS AFTER TREATMENT

- Imaging study 6 weeks after the 2nd TAA-CTL infusion.

To learn more about the way the T cells are working in your body, an extra 20-40 mL (4-8 teaspoons) of blood will be taken before each cycle of aza, 2 weeks after each cycle of aza, before the T-cell infusion, and at Weeks 1, 2, 4 and 6. Afterwards, blood will be collected at 3, 6, 9 and 12 months after the last infusion. The blood may be drawn from your central line at the time of your regular blood tests. We will use this blood to see how long the T cells last, and to look at the immune response to your cancer.

If you receive additional doses of T cells this blood will also be collected pre- each infusion and 1, 2, 4, and 6 weeks post each infusion.

The maximum amount of blood that may be drawn over the course of the study is 180 to 360 teaspoons.

If you decide to withdraw at any time during the study both samples and data collected during your participation will be maintained.

This study will continue until it has completed enrolling subjects.

We may request a sample of a previous tumor biopsy you've had or from a tumor biopsy performed at any time while you are on this study. The sample will be used for research purposes related to this study.

In the event of death, we will request permission to perform an autopsy to learn more about the effects of the treatment on your disease.

STUDY DURATION

Your active participation in this study will last for approximately 1 year and 3 months. If you receive additional doses of the T cells as described above, your active participation will last until 1 year after your last dose of T cells. We will then contact you once a year for up to 4 additional years (total of 5

years follow-up) in order to evaluate your disease response long-term.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning HIV
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, TCH: Texas Children's Hospital, TMH: The Methodist Hospital, and NATIONAL CANCER INSTITUTE (NCI) and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may

share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL CANCER INSTITUTE (NCI) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, Data and Safety Monitoring Board, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: George Carrum, MD
Houston Methodist Hospital, Suite M964
6565 Fannin Street
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

Risks of Blood Draws are possible bleeding and infection at the puncture site. Also, it is possible that a person may faint when blood is drawn.

Risks of T Cell Administration: Similar types of T cells have been given to over 50 patients with lymphoma. Most patients had no side-effects. In some patients with large tumors and/or widespread

disease, the cells have caused inflammation leading to fever and flu-like symptoms, as well as swelling at the tumor site. This swelling could be potentially dangerous and even life-threatening depending on the site. One area of the body where this inflammation could happen is in the lungs. Swelling in the lungs could be severe and possibly life-threatening. If you have such swelling, you may be given steroids which can help to treat this side-effect.

There is also a risk that the cells could cross-react with normal proteins in your body, rather than the tumor-associated antigens, and cause damage to normal organs. We try to reduce this risk by checking the cross-reactivity of the cells before we give them back to you.

A small percentage (less than 1%) of patients that receive this type of therapy develop a life-threatening complication known as a cytokine release syndrome. This complication causes high body temperature, increased heart rate, and low blood pressure. This complication can be life threatening. There are treatments for this complication.

Risks from the Study Drug Azacitidine

You may have side effects while you are in the study, but you will be carefully checked by the study doctor for any problems. There may be risks or side effects of the study drug that are unknown at this time. You should tell the study doctor/staff about anything that is bothering you or any side effects you have, even if you do not think they are related to the study drug.

Azacitidine has been studied in subjects with cancer of the blood and other organs of the body, as well as in subjects with other diseases. The following is a list of the most medically significant or most common side effects reported in completed studies considered to be related to azacitidine. In some cases, side effects can be serious, long-lasting, or can cause death. Some side effects go away soon after you stop the study drug and some may never go away. The study doctor may alter the dosage regimen of azacitidine (if allowed by the study) or give you medicines to help lessen the side effects. This is not a complete list of all side effects that may occur. For more information about risks and side effects, please ask the study doctor.

Very common (a 10% or more chance that this will happen):
- anemia (a decrease in the number of red blood cells which may make you feel weak or tired
- low number of white blood cells with or without fever
- a decrease in the number of platelets, the cells that help your blood to clot
- infections, including pneumonia or of the lung, mouth, skin, or urinary tract (which may be bacterial, fungal or viral)
- nausea
- vomiting
- diarrhea
- stomach pain
- constipation

- feeling tired, unwell, or weak
- fever
- sore throat with swelling or pain of the nasal membranes or nose
- decreased appetite
- weight loss
- low blood levels of potassium
- pain (including muscle, joints, back, and chest pain)
- dizziness
- headache
- difficulty sleeping
- shortness of breath with or without exercise
- rash
- itchiness
- bruising, including tiny red or purple spots under the skin or other tissue
- nosebleed
- injection site reaction, including itching, pain, rash, redness, bleeding, bruising, swelling or damage where the injection/infusion was given

Common (between a 1% to less than 10% chance that this will happen)

- bone marrow failure which is a severe reduction of red and white blood cells and platelets (at nearly the -same time) which can cause weakness, bruising, or make infections more likely
- a very severe infection of the blood which may include a decrease in blood pressure
- shivering (chills)
- indigestion or upset stomach
- a disease affecting the gut which can result in fever, vomiting and stomach pain (diverticulitis)
- pain, swelling, or sores on the inside of the mouth
- runny nose or sinus infection
- bleeding including from the gums, eye, brain, stomach or rectum (hemorrhoids) or due to a catheter line
- muscle spasms
- anxiety
- sleepiness
- blood in the urine
- hair loss
- redness of the skin
- hives
- high blood pressure
- low blood pressure or dizziness upon standing
- fainting
- dehydration
- fluid around the lungs

Uncommon (between a 0.1 to less than 1% chance that this will happen):
- allergic reaction (may include skin inflammation, rash, trouble breathing; trouble speaking; fever, and/or diarrhea)

Rare (less than 0.1% chance that this will happen):
- abnormal kidney function test; kidneys not functioning properly, that has rarely led to too
- much acid in the blood. or kidney failure (sometimes fatal)
- in patients with certain types of cancer, abnormal liver function may occur that has rarely led to decreased level of consciousness related to liver toxicity (sometimes fatal)

Additional side effects observed during post marketing surveillance of azacitidine , not otherwise noted above include:
- rapid death of cancer cells, where the accumulating contents of dying cancer cells cause an imbalance in the chemistry of the body which can lead to kidney damage
- thickening, inflammation, or scarring in the lungs
- open skin sores or tissue damage at the site of injection
- infection of the deeper layers of skin, which may spread quickly, damaging the skin or tissue, which can be life-threatening
- large plum-colored, raised painful patches on the skin with fever.

Some patients taking oral azacitidine have had severe diarrhea. If you experience any diarrhea, or loose watery stools, or notice that you have more stools in a day than usual, it is important that you notify your study doctor so that he or she can give you medication to control this side effect and adjust your dose of oral azacitidine if needed.

Pregnancy Risk

Females: Azacitidine can cause harm to an unborn child if given to a pregnant woman. You cannot take part in this study if you are pregnant or breast-feeding. Because of the possible risks to an unborn child, if you are a female who can become pregnant, you will be asked to take a pregnancy test prior to starting study drug treatment and throughout your study participation.

If you decide to take part in this study, you should avoid becoming pregnant while receiving study medication. You must agree to complete abstinence from heterosexual contact , or agree to use effective contraception without interruption , while receiving study medication or for a longer period if required by local regulations. If you become pregnant while receiving study medication or within the length of time instructed by your physician to avoid pregnancy, whichever is longer, you must tell the study doctor right away. If you become pregnant while on study medication, the study medication will be discontinued. The study doctor will follow you until completion of your pregnancy. After your child is born the sponsor would like to follow them for 1 year. You would be asked to give permission for that follow-up at that time.

Males: If you have a female partner of childbearing potential, you should not father a child while receiving study medication and must agree to complete abstinence from heterosexual contact or use effective contraception without interruption, while receiving study medication, or longer if required by local regulations. If your partner becomes pregnant while you are receiving study medication or within the length of time instructed by your physician to avoid fathering a child, whichever is longer, you must tell the study doctor right away.

Risks of Acetaminophen (Tylenol): Rarely, large doses or long-term usage can cause liver damage, rash, itching, fever, and/or lowered blood sugar. These side-effects are unlikely at the doses being used for this study.

Risks of Diphenhydramine (Benadryl) include drowsiness, dizziness, headache, irritability, stomach upset, vision changes (e.g. blurred vision), decreased coordination, and/or dry mouth/nose/throat.

General: Because of potential or unknown effects of the study on a fetus, if you are a woman of child-bearing potential, you must have a negative pregnancy test prior to the first infusion of T cells.

We will watch you very carefully for any side-effects. If there are bad side-effects, we will stop the treatment.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: It is possible that your immune system may begin to kill the cancer cells, making the lymphoma go into remission or go away. Additionally, your participation may help the investigators better understand how the immune system can fight Hodgkin and non-Hodgkin lymphoma. This could benefit other patients with lymphoma. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: No further treatment, or other treatment with chemotherapy and radiation. Your doctor will discuss these other options with you. Additionally, the same alternatives are available if after participation in this research project you are not responding to the therapy.

Subject Costs and Payments

You will not be charged for the manufacture or preparation of the T cell product, for the drug azacytidine, or for any evaluations that are being done solely as part of your participation in this research project. You may be charged for some research-related costs, including the infusion of the T-cell product or the azacytidie. You will be charged for any tests or treatments that are being done as standard treatment for Hodgkin disease or non-Hodgkin lymphoma.

You will not be paid for taking part in this study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Research Related Injury

If you are injured as part of your participation in this study, there are no plans to pay you.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Women of Childbearing Potential

It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. Because of the potential risks involved, you or your partner should not become pregnant while you are participating in this study.

If you are sexually active or become sexually active and can get pregnant or can get your partner pregnant, you must agree to use one of the following forms of birth control every time you have sex and for (6) months afterwards:

* oral contraceptives ("the pill"),
* intrauterine devices (IUDs),
* contraceptive implants under the skin, or contraceptive injections,
* condoms with foam.

Should you become pregnant while on this study, you must immediately notify the study personnel.

The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can choose not to provide this information.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, GEORGE CARRUM, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: DR. GEORGE CARRUM during the day and after hours at 713-441-1450.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

The National Institutes of Health (NIH) and the National Cancer Institute (NCI) may have access to your records for research purposes. Coded information may be provided to the NIH/NCI such as Patient ID, Patient zip code, Patient country code, and Patient birth date (month/year). However, in the event of an audit NIH/NCI might have access to more information that is part of your research record.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

H-27471- ADMINISTRATION OF TUMOR-ASSOCIATED ANTIGEN (TAA)-SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH ACTIVE OR RELAPSED HODGKIN OR NON-HODGKIN LYMPHOMA (TACTAL)

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date

H-27471- ADMINISTRATION OF TUMOR-ASSOCIATED ANTIGEN (TAA)-SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH ACTIVE OR RELAPSED HODGKIN OR NON-HODGKIN LYMPHOMA (TACTAL)

Background

This is a clinical trial, a type of research study. Your doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You have a type of lymph gland disease called Hodgkin or non-Hodgkin lymphoma which has come back, or may come back, or has not gone away after treatment, including the standard treatment we know for these diseases. We are asking you to volunteer to be in a research study using special immune system cells called tumor-associated antigen (TAA)-specific cytotoxic T lymphocytes, a new experimental therapy.

We have previously used this sort of therapy to treat Hodgkin or non-Hodgkin lymphoma that shows proof of infection with the virus that causes infectious mononucleosis ("mono" or the "kissing disease"), Epstein-Barr virus (EBV). EBV is found in cancer cells of up to half of all patients with Hodgkin's and non-Hodgkin lymphoma. This suggests that it may play a role in causing lymphoma. The cancer cells infected by EBV are able to hide from the body's immune system and escape being killed. We previously tested whether special white blood cells, called T cells, that were trained to kill EBV-infected cells could affect these tumors, and in many patients we found that giving these trained T cells caused a complete or partial response.

However, many patients do not have EBV in their lymphoma cells; therefore we now want to test whether special T lymphocytes directed against other types of proteins that show on the tumor cell surface can result in similar promising results. The proteins that we will target in this study are called tumor-associated antigens (TAAs) - these are cell proteins that are specific to the cancer cell, so they either do not show or show up in low quantities on normal human cells.

In this stage of the study we will target five TAAs which commonly show on lymphoma cells, called NY-ESO-1, MAGEA4, PRAME, Survivin and SSX. We will do this by using special types of T cells called cytotoxic T lymphocytes (CTLs) generated in the lab. These TAA-specific T cells are an investigational product not yet approved by the U.S. Food and Drug Administration.

Baylor College of Medicine has a financial interest with Marker Therapeutics, LLC, a licensee of Baylor College Medicine patented technologies. The study staff (Dr. Heslop, Dr. Leen and Dr. Rooney) also have a financial interest in the development of the study drug. They may benefit financially if this research leads to future treatment options. Please feel free to ask the study team if you have any questions about this relationship.

This research study is sponsored by a NCI Lymphoma Specialized Program in Research Excellence (SPORE) grant.

H-27471- ADMINISTRATION OF TUMOR-ASSOCIATED ANTIGEN (TAA)-SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH ACTIVE OR RELAPSED HODGKIN OR NON-HODGKIN LYMPHOMA (TACTAL)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose
The purpose of this stage of the study is to find out if TAA-specific cytotoxic T cells are safe in children. We want to learn what the side-effects are, and to see whether this therapy might help patients with Hodgkin disease or non-Hodgkin lymphoma.

Procedures
The research will be conducted at the following location(s):
Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

At most, 15 people may be treated on this stage of the study.

Earlier, you gave blood for us to make TAA-specific cytotoxic T cells in the lab. These cells were grown and frozen for you.

If the TAA-specific cytotoxic T cells can be made, the time from collection of the blood to manufacture of T cells for administration to the patient is about 1 to 2 months.

The cells will then be injected by IV into you over 10 minutes. You may be pre-treated with acetaminophen (Tylenol) and diphenhydramine (Benadryl). Acetaminophen (Tylenol) and diphenhydramine (Benadryl) are given to prevent a possible allergic reaction to the T cell administration. Initially, two doses of T cells will be given two weeks apart. Your lymphoma will be assessed pre-infusion and then 6 weeks after the second infusion. If after your second infusion there is a reduction in the size of your lymphoma on CT or MRI scan as assessed by a radiologist, you can receive up to six (6) additional doses of the T cells at 6-8 week intervals if you wish. All of the treatments will be given by the Center for Cell and Gene Therapy at Texas Children's Hospital.

In between the first and second T cell infusions and for 6 weeks after the last infusion, we ask that you not receive any other anti-cancer treatments such as radiation therapy or chemotherapy. If you do receive any other therapies in-between the first and second infusion of T cells, you will be taken off treatment and will not be able to receive the second infusion of T cells.

MEDICAL TESTS BEFORE TREATMENT

Before being treated, you will receive a series of standard medical tests:
- Physical exam.
- Blood tests to measure blood cells, kidney and liver function.
- Measurements of your tumor by routine imaging studies. We will use the imaging study that was used before to follow your tumor: CT, MRI, or PET.
- Pregnancy test if you are a female who can have children.

MEDICAL TESTS AFTER TREATMENT

- Imaging study 6 weeks after the 2nd TAA-CTL infusion.

To learn more about the way the T cells are working in your body, an extra 20-40 mL (4-8 teaspoons) of blood or 3ml/kg of body weight of blood (whichever is less) will be taken before the infusion, and at weeks 1, 2, 4 and 6. Afterwards, blood will be collected at 3, 6, 9 and 12 months after the last infusion. The blood may be drawn from your central line at the time of your regular blood tests. We will use this blood to see how long the T cells last, and to look at the immune response to your cancer.

If you receive additional doses of T cells this blood will also be collected pre- each infusion and 1, 2, 4, and 6 weeks post each infusion.

The maximum amount of blood that may be drawn over the course of the study is 156 to 312 teaspoon.

If you decide to withdraw at any time during the study both samples and data collected during your participation will be maintained.

This study will continue until it has completed enrolling subjects.

We may request a sample of a previous tumor biopsy you've had or from a tumor biopsy performed at any time while you are on this study. The sample will be used for research purposes related to this study.

In the event of death, we will request permission to perform an autopsy to learn more about the effects of the treatment on your disease.

STUDY DURATION

Your active participation in this study will last for approximately one 1 year. If you receive additional doses of the T cells as described above, your active participation will last until one 1 year after your last dose of T cells. We will then contact you once a year for up to 4 additional years (total of 5 years follow-up) in order to evaluate your disease response long-term.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning HIV
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, TCH: Texas Children's Hospital, TMH: The Methodist Hospital, and NATIONAL CANCER INSTITUTE (NCI) and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital maintain in a designated record set, which means a set of data that

includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL CANCER INSTITUTE (NCI) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, Data and Safety Monitoring Board, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: George Carrum, MD
Houston Methodist Hospital, Suite M964
6565 Fannin Street
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

Risks of Blood Draws are possible bleeding and infection at the puncture site. Also, it is possible that a person may faint when blood is drawn.

Risks of T Cell Administration: Similar types of T cells have been given to over 50 patients with lymphoma. Most patients had no side-effects. In some patients with large tumors and/or widespread disease, the cells have caused inflammation leading to fever and flu-like symptoms, as well as swelling at the tumor site. This swelling could be potentially dangerous and even life-threatening depending on the site. One area of the body where this inflammation could happen is in the lungs. Swelling in the lungs could be severe and possibly life-threatening. If you have such swelling, you may be given steroids which can help to treat this side-effect.

There is also a risk that the cells could cross-react with normal proteins in your body, rather than the tumor-associated antigens, and cause damage to normal organs. We try to reduce this risk by checking the cross-reactivity of the cells before we give them back to you.

A small percentage (less than 1%) of patients that receive this type of therapy develop a life-threatening complication known as a cytokine release syndrome. This complication causes high body temperature, increased heart rate, and low blood pressure. This complication can be life threatening. There are treatments for this complication.

Risks of Acetaminophen (Tylenol): Rarely, large doses or long-term usage can cause liver damage, rash, itching, fever, and/or lowered blood sugar. These side-effects are unlikely at the doses being used for this study.

Risks of Diphenhydramine (Benadryl) include drowsiness, dizziness, headache, irritability, stomach upset, vision changes (e.g. blurred vision), decreased coordination, and/or dry mouth/nose/throat.

General: Because of potential or unknown effects of the study on a fetus, if you are a woman of child-bearing potential, you must have a negative pregnancy test prior to the first infusion of T cells.

We will watch you very carefully for any side-effects. If there are bad side-effects, we will stop the treatment.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: It is possible that your immune system may begin to kill the cancer cells, making the lymphoma go into remission or go away. Additionally, your participation may help the investigators better understand how the immune system can fight Hodgkin and non-Hodgkin lymphoma. This could benefit other patients with lymphoma. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: No further treatment, or other treatment with chemotherapy and radiation. Your doctor will discuss these other options with you. Additionally, the same alternatives are available if after participation in this research project you are not responding to the therapy.

Subject Costs and Payments

You will not be charged for the manufacture or preparation of the T cell product, or for any evaluations that are being done solely as part of your participation in this research project. You may be charged for some research-related costs, including the infusion of the product. You will be charged for any tests or treatments that are being done as standard treatment for Hodgkin disease or non-Hodgkin lymphoma.

You will not be paid for taking part in this study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Research Related Injury

If you are injured as part of your participation in this study, there are no plans to pay you.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Women of Childbearing Potential

It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. Because of the potential risks involved, you or your partner should not become pregnant while you are participating in this study.

If you are sexually active or become sexually active and can get pregnant or can get your partner pregnant, you must agree to use one of the following forms of birth control every time you have sex and for (6) months afterwards:

* oral contraceptives ("the pill"),
* intrauterine devices (IUDs),
* contraceptive implants under the skin, or contraceptive injections,
* condoms with foam.

Should you become pregnant while on this study, you must immediately notify the study personnel.

The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can choose not to provide this information.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and

services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, GEORGE CARRUM, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: DR. RAYNE ROUCE at 832-824-4716 during the day and 832-826-0860 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

The National Institutes of Health (NIH) and the National Cancer Institute (NCI) may have access to your records for research purposes. Coded information may be provided to the NIH/NCI such as Patient ID, Patient zip code, Patient country code, and Patient birth date (month/year). However, in the event of an audit NIH/NCI might have access to more information that is part of your research record.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here _____

H-27471- ADMINISTRATION OF TUMOR-ASSOCIATED ANTIGEN (TAA)-SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH ACTIVE OR RELAPSED HODGKIN OR NON-HODGKIN LYMPHOMA (TACTAL)

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Legally Authorized Representative Parent or Guardian	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date